(12) UK Patent Application (19) GB (11) 2 148 841 A

(43) Application published 5 Jun 1985

(21) Application No 8427523

(22) Date of filing 31 Oct 1984

(30) Priority data

(31) 548794 (32) 4 Nov 1983 (33) US
641664 17 Aug 1984

(51) INT CL[4]
A61K 9/48

(52) Domestic classification
B8C A

(56) Documents cited
GB A 2079238
GB A 2050286
GB 1465383
GB 1347189

(58) Field of search
B8C

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(54) Capsulated medicaments

(57) A divisible hard shell capsule in dosage form, has a plurality of connected subunits each comprising a joined or joinable cap part (2) and body part (1), wherein the body parts (1) are joined by connection elements (5) and/or cap parts (2) are joined by connection elements (5), the connection elements (5) being integrally moulded with the body parts (1) and/or the cap parts (2), and the connection elements (5) being breakable whereby the capsule may be divided into subunits.

A compartmented hard shell capsule in dosage form, comprises a joined or joinable cap part (2) and body part (1), wherein the body part (1) has one or more internal partitions integrally moulded therein so as to form two or more compartments intended for medicaments within the body (1) and the cap (2), when joined, for pharmaceutical dosage.

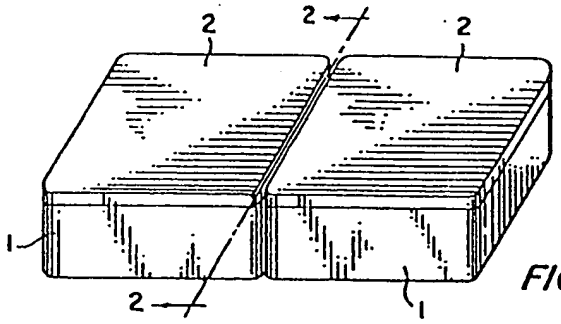

FIG. 1

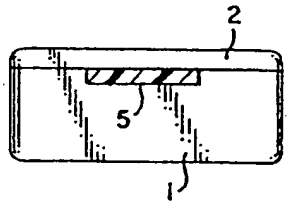

FIG. 2

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The drawings originally filed were informal and the print here reproduced is taken from a later filed formal copy.

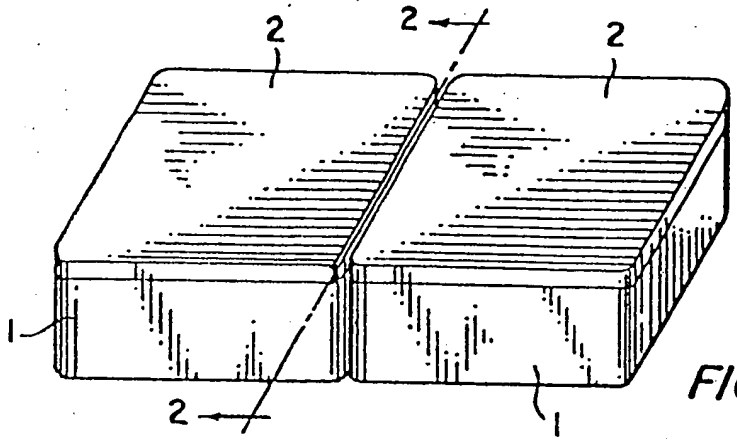

FIG. 1

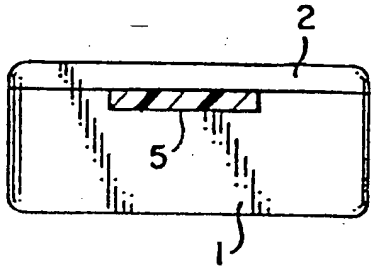

FIG. 2

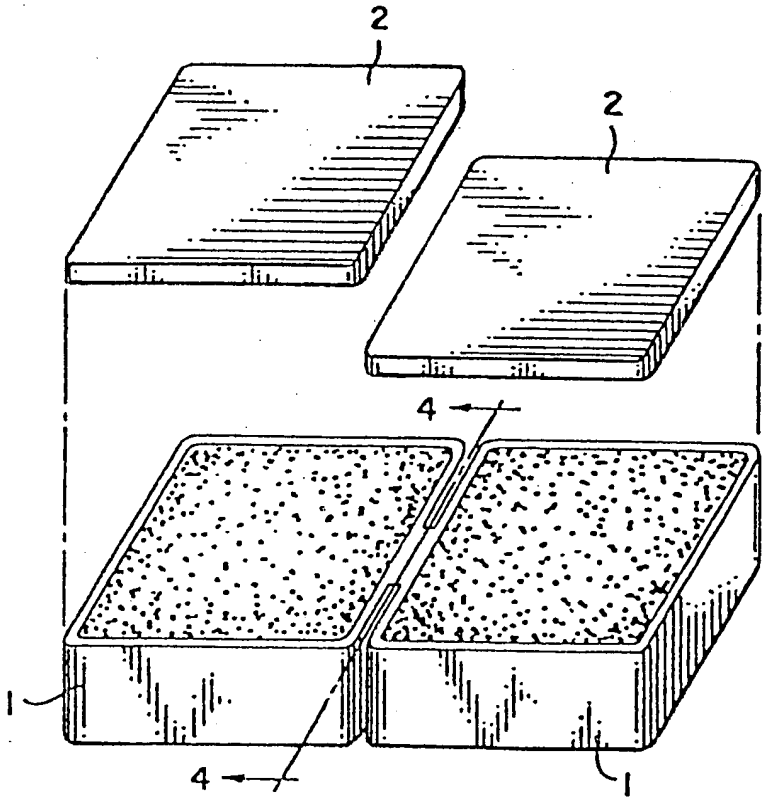

FIG3

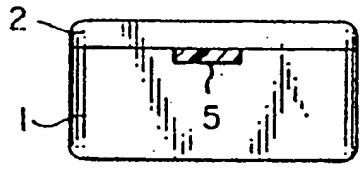

FIG. 4

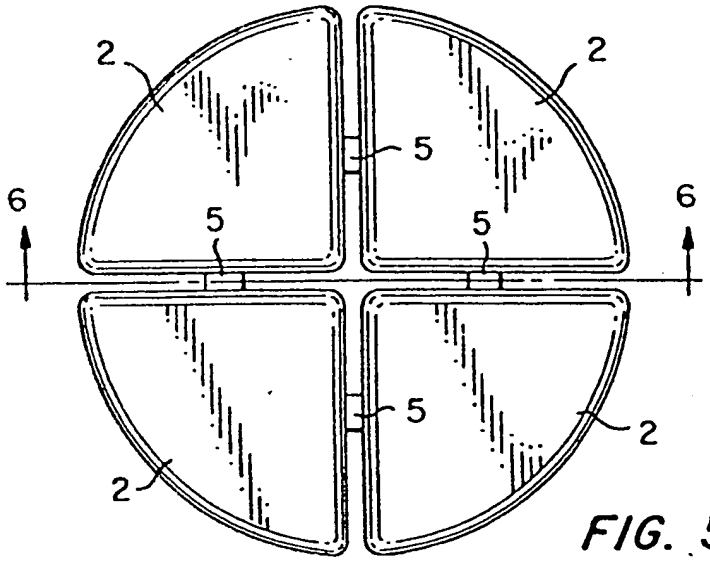

FIG. 5

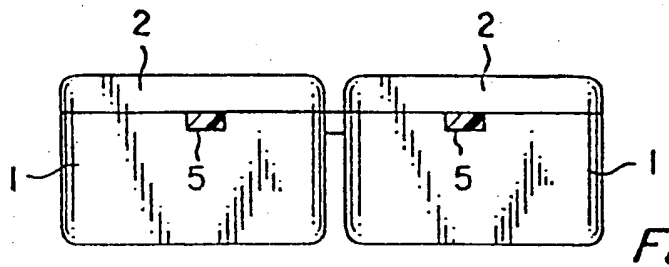

FIG. 6

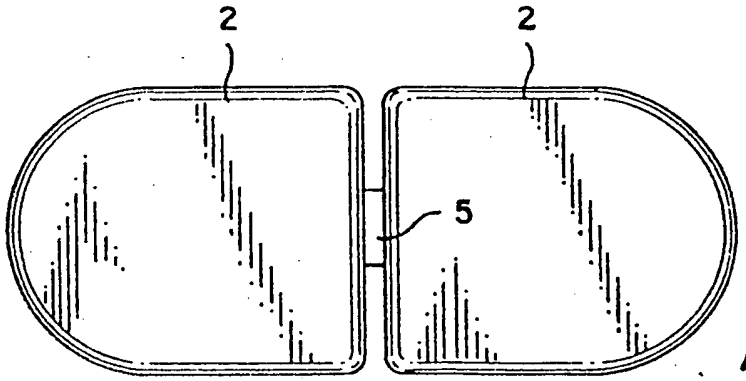

FIG. 7

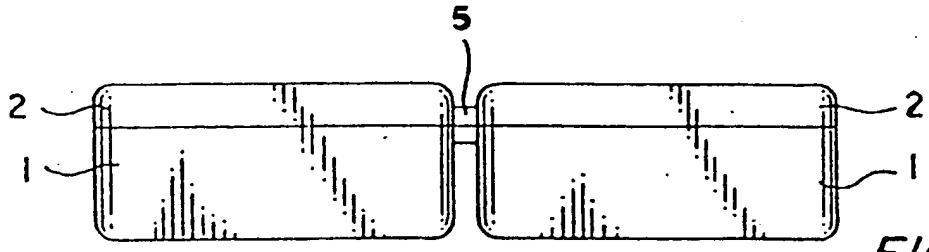

FIG. 8

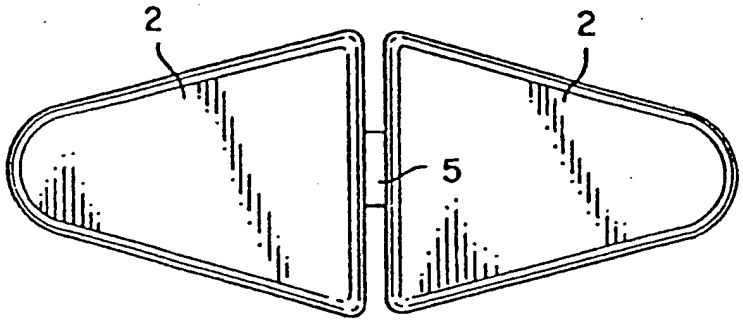

FIG. 9

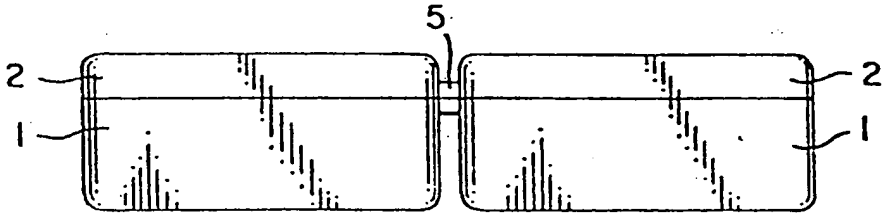

FIG. 10

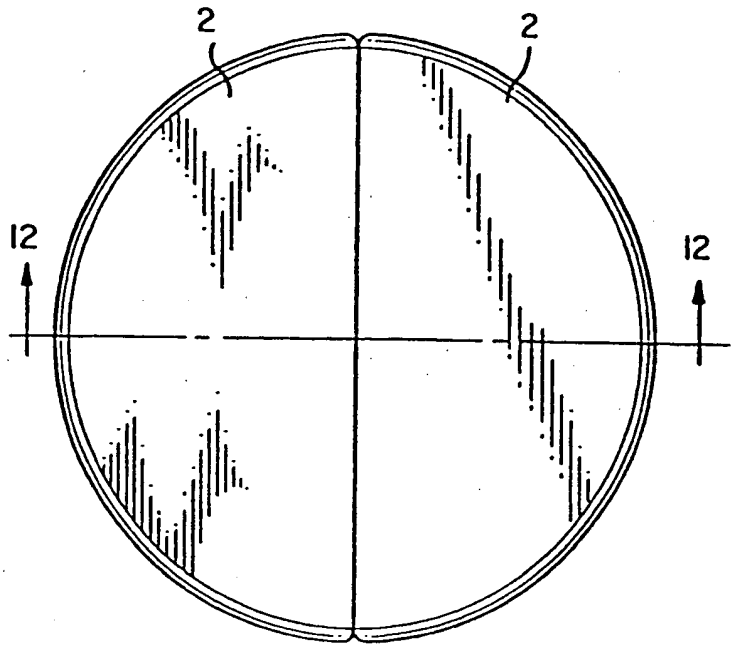

FIG. 11

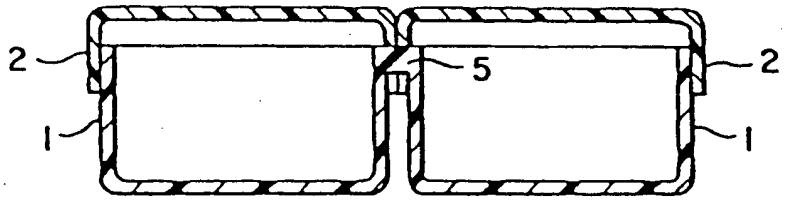

FIG. 12

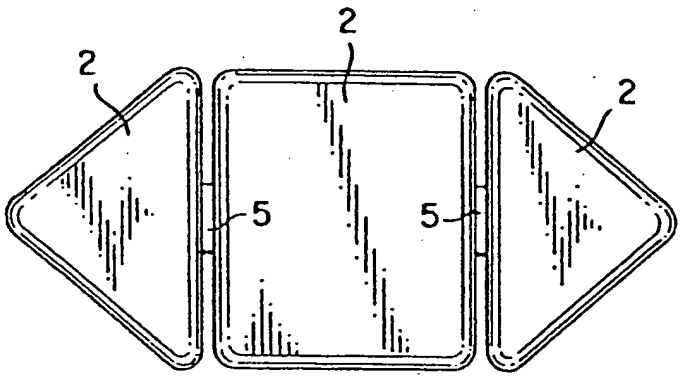

FIG. 13

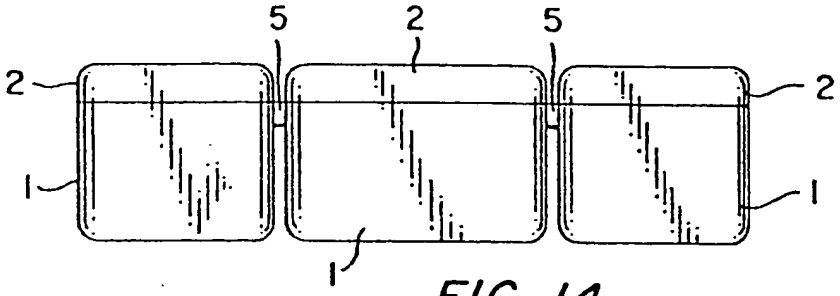

FIG. 14

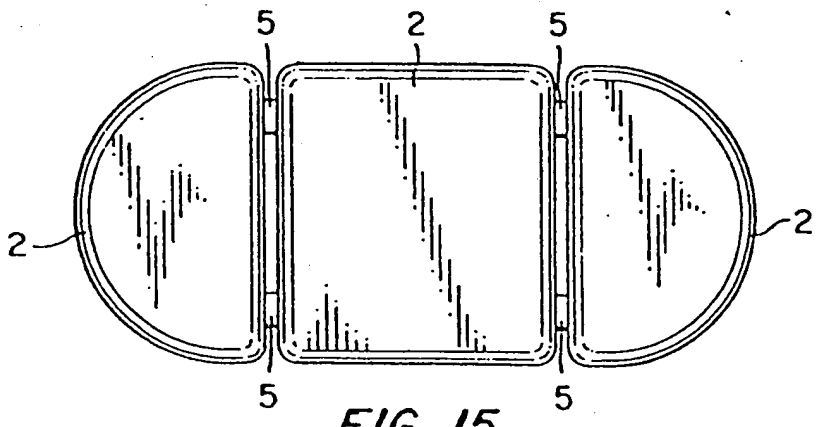

FIG. 15

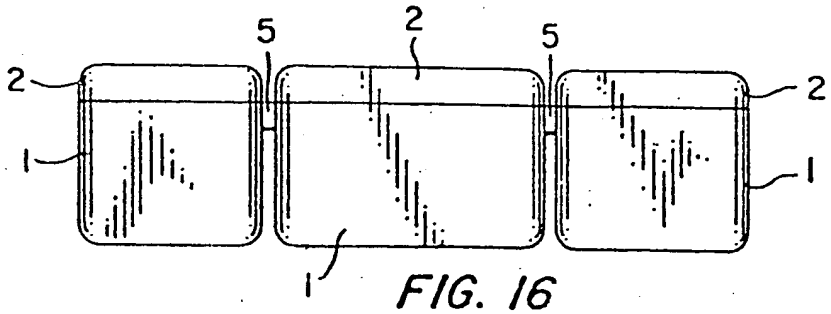

FIG. 16

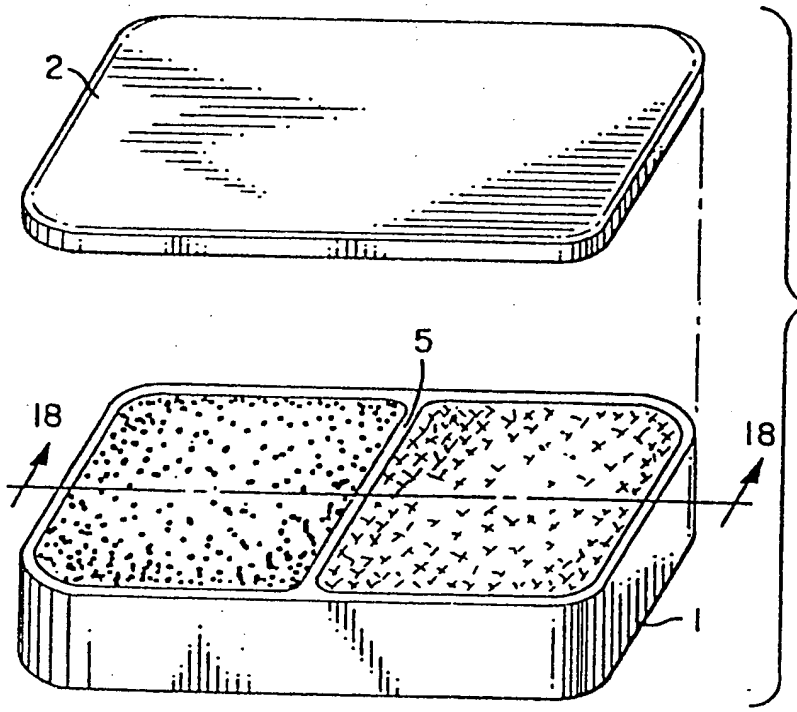

FIG. 17

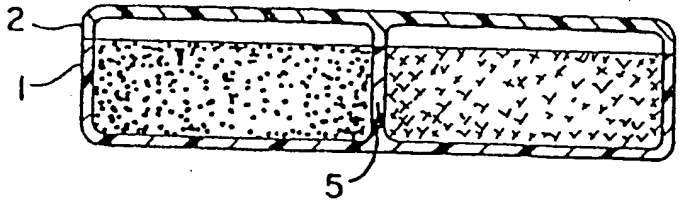

FIG. 18

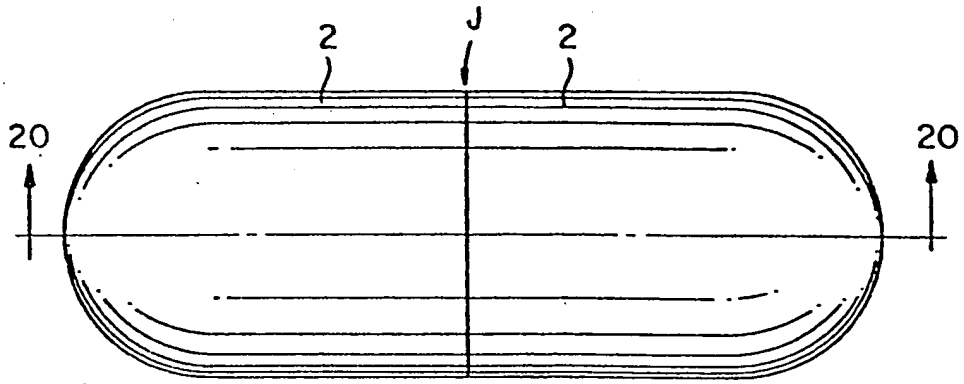

FIG. 19

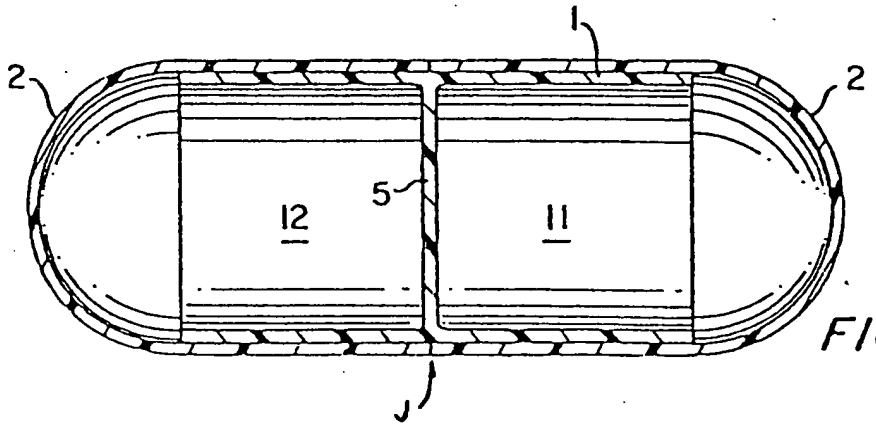

FIG. 20

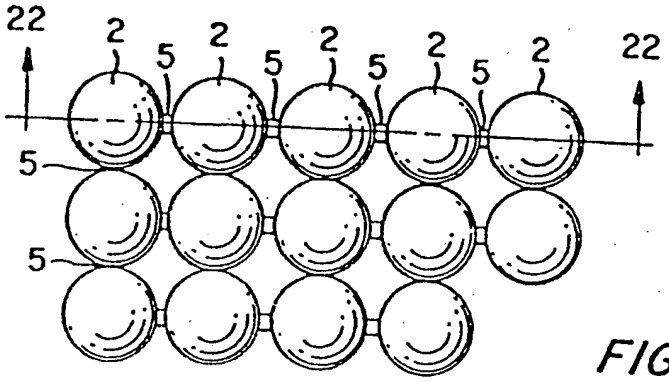

FIG. 21

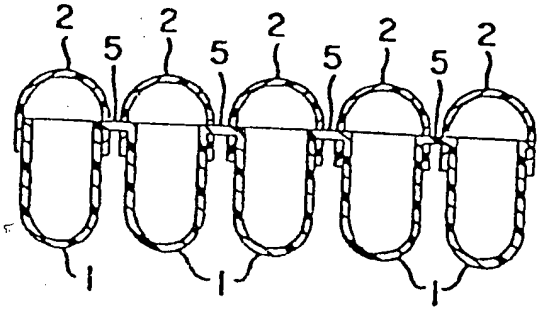

FIG. 22

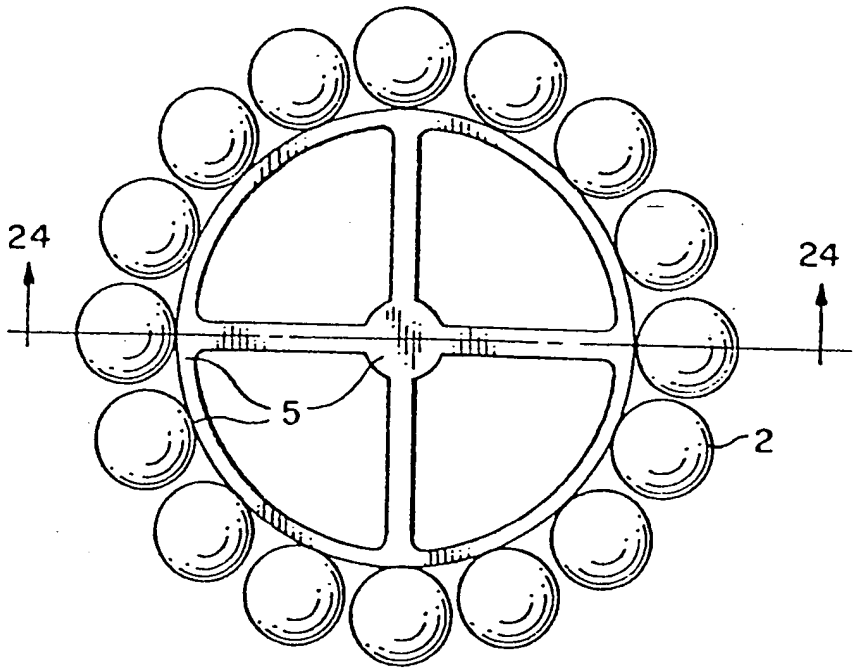

FIG. 23

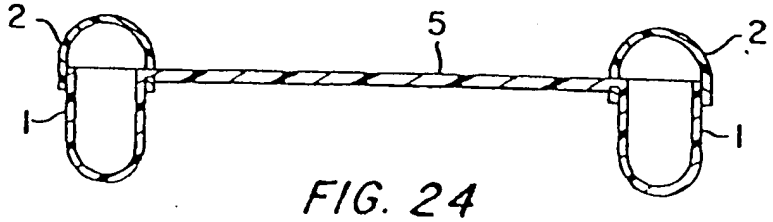

FIG. 24

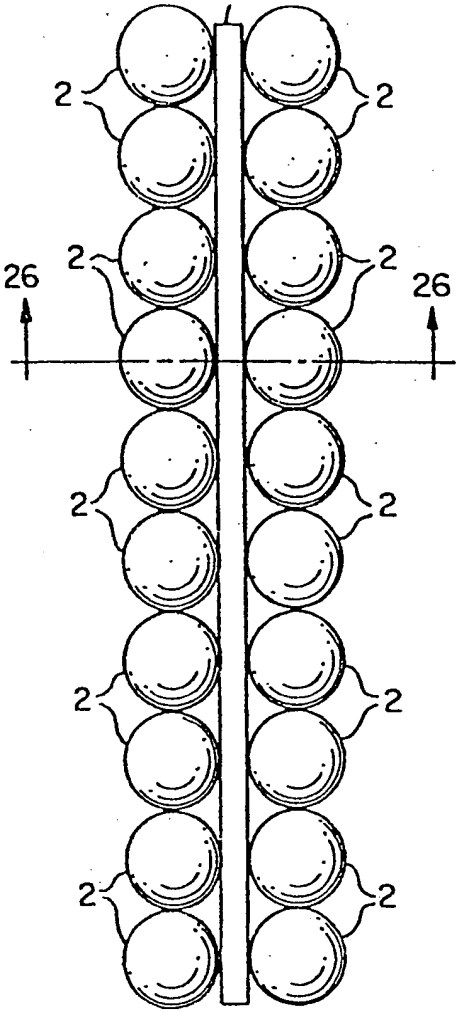

FIG. 25

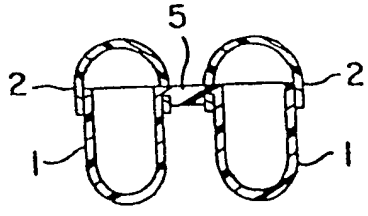

FIG. 26

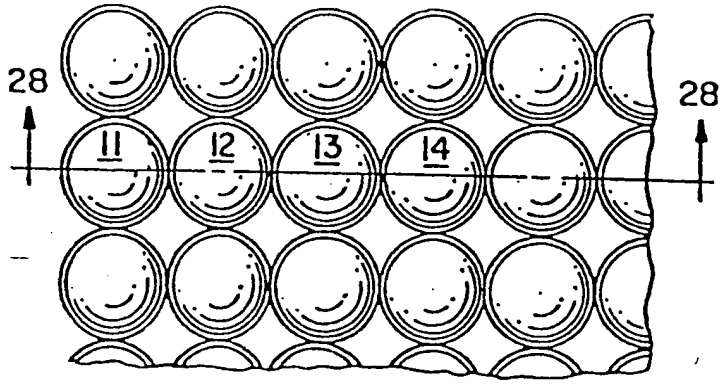

FIG. 27

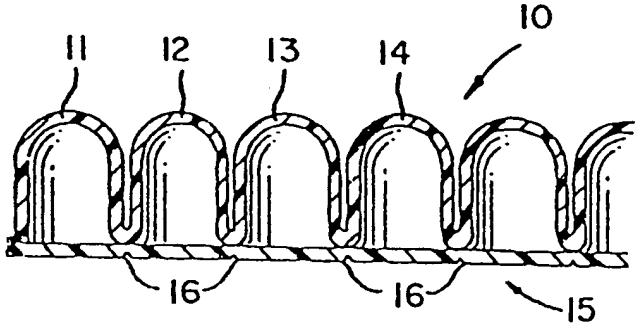

FIG. 28

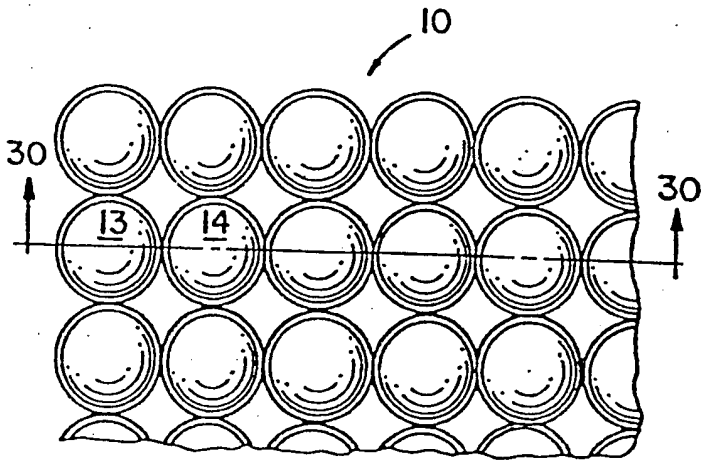

FIG. 29

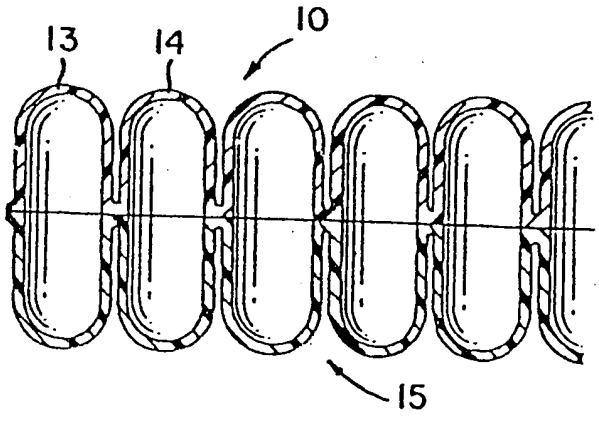

FIG. 30

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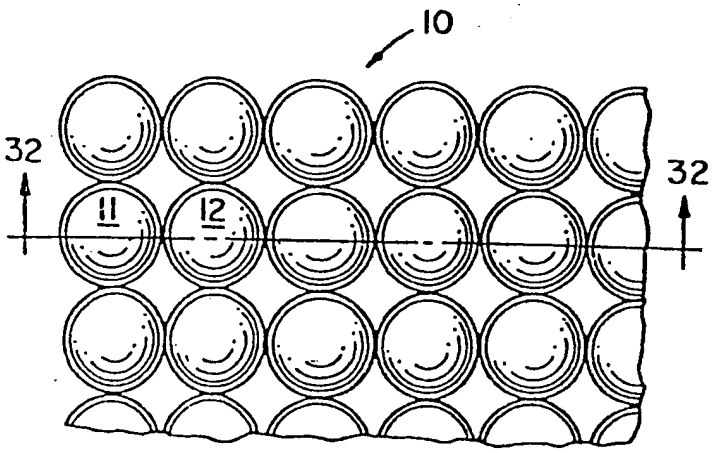

FIG. 31

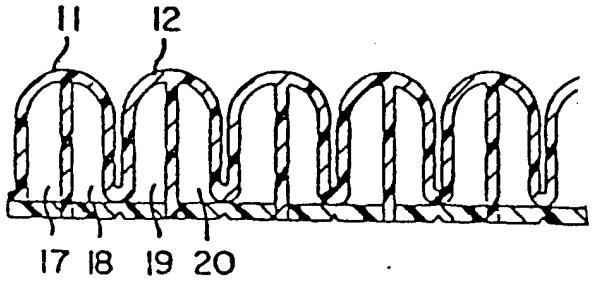

FIG. 32

SPECIFICATION

Capsule dosage forms

The present invention relates to a hard shell capsule dosage form for solid, creamy or liquid substances, especially for pharmaceutical use.

The dosage form of this invention consists of two or more capsules which are connected to each other. The connections between the capsules may be manufactured simultaneously with the capsule by die-molding techniques and may consist of the same material as the capsules themselves. The capsules may be divided by breaking the connections.

The capsules may be formed with two or more non-separable compartments within each capsule for containing different medicaments therein.

Both the divisible and the compartmented capsules may be formed simultaneously as a multiple unit dosage or package.

Prior art hard shell capsules for pharmaceutical use consist of one unit which has only one filling compartment formed by axially joinable cylindrical cap and body parts. Due to the limitation of manufacture by the prior art dip-molding process, the prior art capsules cannot be attached one to another during the manufacturing process.

It is known that tablets provide a way for patients to choose the dosage by breaking the tablet into pieces.

With the present invention it is possible to make combinations of two or more medicaments which cannot be combined in a tablet or in a prior art capsule because they tend to react with each other to yield unsuitable products.

With the present invention capsule dosage forms can be provided which can be divided into subunits to be swallowed.

In addition, with the present invention it is possible to provide capsules to be filled with two or more different medicaments.

The articles of the present invention can be formed by die pressure-molding of starch, hydrophilic polymers like gelatin or starch derivatives, all with a low water content.

The present invention especially relates to certain structures and forms of such die-molded capsules, especially injection-molded capsules.

The present invention provides for a divisible hard shell capsule dosage form having a plurality of connected subunits consisting of cap parts and body parts being joinable characterized in that said body parts have a lamella connection together, said connection being integrally molded with said body parts, and said connection further being breakable so as to separate the capsule into subunits especially for pharmaceutical dosage.

The present invention provides further a compartmented hard shell capsule dosage form consisting of a cap part and a body part characterized in that said body part has one or more internal partitions integrally molded therein so as to form two or more compartments especially for medicaments within said body and said cap, when joined, for pharmaceutical dosage.

The present invention provides also a hard shell capsule package dosage form having a plurality of connected capsules consisting of cap parts and body parts being joinable characterized in that said capsules have a connection together, said connection being integrally molded with said capsules, and said connection further being breakable so as to separate the capsule into individual capsules especially for pharmaceutical dosage.

In die-molding such as injection-molding it is important that the material to be molded shows the quality of a thermoplastic material during the molding process and that the material hardens quickly in the mold so that it can be ejected rapidly without changing its dimensions. The latter is an important factor as the accuracy of very many die-pressure molded articles must be within very narrow limits.

The present invention provides also capsule dosage forms as described herein, characterized in that this capsule dosage form is made by injection molding:

(i) from a hydrophilic polymer composition or a mixture of such polymers having a water content of 5-25% by weight (calculated to the hydrophilic polymer composition) and if formed from gelatin composition said gelatin composition having a water content of 10-20% by weight (calculated to the gelatin composition); and/or

(ii) from a starch or a starch composition having a water content of 5-25% by weight (calculated to the starch composition).

Preferred capsules, according to this invention, are made from starch and by injection-molding.

The injection-molding of hydrophilic materials such as gelatin containing water has been described in European Patent Application Publication No. 92908.

Hydrophilic polymers are polymers with molecular masses from approximately 10^3 to 10^7 Dalton carrying molecular groups in their backbone and/or in their side chains and capable of forming and/or participating in hydrogen bridges. Said hydrophilic polymers have a water content of 5 to 25% by weight of said hydrophilic polymer water composition and the working temperature for injection molding of said hydrophilic polymers is in the range between 50°C and 190°C, preferably 80°C to 190°C.

Gelatin as a hydrophilic polymer is made from various types of gelatin, including acid or alkaline processed ossein, acid processed pigskin, or alkaline processed cattle hide. Said types of gelatin have a molecular preferably in the mass range of 10.000 to 2×10^7 Dalton or a molecular mass range of 10.000 to 2×10^6 and 10×10^6 to 20×10^6 Dalton. It has a water content of preferably 10-19% and especially 12-18% by weight calculated to the gelatin.

All the hydrophilic polymers, gelatin included, may also contain various additives such as plasticizers, lubricants, cross-linking and coloring agents as described in European Patent Application Publication No. 92908 in concentrations indicated in

said European Patent Application. The polymers may also contain extenders up to 95% and preferably not more than 30% by weight such as proteins like sunflower proteins, soybean proteins, cotton seed proteins, peanut proteins, blood proteins, egg proteins, rape seed proteins and acetylated derivatives thereof, gelatin, crosslinked gelatin, vinyl-acetate, polysaccharides as cellulose, methylcellulose, hydroxypropyl-cellulose, hydroxypropyl-methylcellulose, hydroxymethyl-cellulose, hydroxyethylcellulose, sodium carbody methylcellulose, agar-agar, gum arabic, guar, dextran, chitin, polymaltose, polyfructose, pectin, alginates, alginic acids, monosaccharides pref. glucose, fructose, saccharose, oligosaccharides pref. lactose, polyvinyl-pyrrolidone, silicates, bentonite, carbonates and bicarbonates.

Such hydrophilic polymers are hydroxypropyl methylcellulosephthalate (HPMCP), polyvinylacetate-phtalate (PVAP), celluloseacetylphthalate (CAP), acrylates and methacrylates (Eudragit), phthalated gelatin, succinated gelatin, crotonic acid, and shellac. These polymers are preferred when enteric properties are required. They contain preferably 5-25% of water, preferably 15-22% by weight, calculated to the waterfree polymer. Preferred is HPMCP, PVAP and CAP, and especilly PVAP and CAP; most preferred is PVAP, all being worked by injection molding having a water content of 5% to 25%, preferably of 15% to 22% by weight.

Some of these polymers are non-thermoplastic and it is very surprising that they can be die-molded according to this invention.

Molding temperatures range from 50 to 190°C and pressures from 600 to 3.000 × 10^5 N/m². Known apparatus can be used.

Preferred is a moldable starch composition made from corn, wheat, potatoes, rice and tapioca.

The starch contains about 0 to 100% of amylose, and about 100 to 0% of amylo-pectin; preferably 0 to 70% of amylose, and about 100 to 30% of amylopectin and most preferably potato starch and maize starch.

When in the following description the terms 'gelatin' or 'starch' are used, this also includes foams, modifications or derivatives of starch, and combinations thereof with other polymer compositions whose properties are acceptable for the intended die-molded capsules.

The starch has a water content of 5-25%, preferably of 15-22% and especially of 17-20%.

This starch may contain various additives such as plasticizers, lubricants, cross-linking and/or coloring agents, as well as extenders. All these are the same as mentioned above for the hydrophilic materials.

Molding temperatures for starch are 80-240°C with pressures ranging from 600 to 3.000 × 10^5 N/m².

The starch containing the water and optionally further additives is molten under these temperatures and pressures in a manner known per se and in molding apparatuses known per se.

Those skilled in the art will be able to work with die-molding, i.e., profile extrusion, compression molding, vacuum forming, thermal forming, extrusion molding, polymer casting in combination with vacuum forming. Preferred, however, is injection-molding.

The advantage of the present invention will become apparent to those skilled in the art by consideration of the detailed description which follows with reference to the accompanying drawings.

In the following description is it convenient to group the embodiments of the present invention into three categories:

1. *Divisible capsule*

The divisible capsule form can be swallowed as a whole, or it can be separated into pieces which can also be swallowed individually. Therefore, the initial capsule as well as the separated pieces are in an easy-to-swallow outer shape which may also be adapted to the field of application.

This is a divisible hard shell capsule dosage form having a plurality of connected subunits consisting of cap parts and body parts being joinable and containing medicaments therein, characterized in that said body parts have a lamella connection together, said connection being integrally molded with said body parts, and said connection further being breakable so as to separate the capsule into subunits especially for pharmaceutical dosage.

Also the cap parts may have a lamella connecting together. Also either of the capsule parts may be a blister sheet and the other capsule part is a blister cover sheet sealed by heat and pressure thereto.

An embodiment of this group is shown in Figures 1, 2, 3 and 4. Figure 1 along line 2-2, the two bodies 1 are connected by a weak joining lamella 5. The two caps 2 are not connected. In Figure 3, which is an exploded view of Figure 1, the dosage form is shown after filling but before the caps 2 are put onto the bodies 1. Figure 4 is a side view of Figure 3 after the caps 2 have been put onto the bodies 1. The embodiment shown in the Figures 1 to 4 may be swallowed as a whole capsule in the initial state, and this dosage form can also be swallowed after it has been separated into two subunits along the lamella 5 whereby each of the subunits can be swallowed individually.

The two subunits of the divisible capsule shown in Figures 1 to 4 may be filled with different or with the same medicaments. In case the capsule is filled with the same medicament, the amount of the dosage can be divided by breaking the form into two pieces. In case the capsule is filled with two different medicaments – one in each subunit – the desired medicament can be swallowed by breaking the capsule at the lamella. In order to identify the content of each subunit, the colors of the subunit may be different or the subunits may be differently imprinted.

The capsule parts 1, 2 and the connecting lamella 5 can be manufactured simultaneously by die-molding, preferably by injection-molding. The connection 5 consists of the same material as the capsule parts 1 and 2.

Figures 5 and 6 show another embodiment of the capsule having four subunits. Figure 5 is a top plan view and Figure 6 is a side view of Figure 5 showing four caps 2 and four bodies 1 connected by weak lamella joinings 5 so as to provide breaking possibilities. This embodiment may be swallowed as a whole or as three, two or only one subunit. Also the different subunits of the capsule may be filled with different or the same medicaments.

Alternative embodiments are shown in Figures 7 to 12. The reference numerals used in Figures 7 to 12 are the same as those used in Figures 1 to 6. In these embodiments the body parts 1 and the cap parts 2 are connected by weak joinings 5 as shown in Figures 11 and 12. The cap parts 2 may overlap the body parts 1. Also, the cap parts 2 may have a recess 6 at the place where the connecting lamella 5 is located so that the lamella 5 is hardly seen even after the capsule has been broken into its subunits.

Another embodiment is shown in Figures 13 and 14, wherein the capsule has three subunits having an inner and two outer parts, each of which again consist of a body part 1 and a cap part 2. In Figures 13 and 14 the outer parts are formed as triangles. Alternately, the outer parts in the Figures 15 and 16 have the shape of semicircles. In the embodiments of the Figures 13 to 16 only the body parts 1 are connected by the lamellas 5 whereas the cap parts 2 are separate pieces.

2. *Compartmented capsule*

The compartmented capsule has two or more compartments for medicaments. It cannot be broken into subunits but it can be filled with two or more different medicaments to be swallowed simultaneously. It is an advantage of die-molding technique that the number of the compartments is not at all limited to two but can be as required by the field of application.

This embodiment is a compartmented hard shell capsule dosage form consisting of a cap part and a body part characterized in that said body part has one or more internal partitions integrally molded therein so as to form two or more compartments especially for medicaments within said body and said cap, when joined, for pharmaceutical dosage.

Such a compartmented hard shell capsule may be characterized in that said body part is tubular with an internal partition perpendicular to the axis and parallel to the opposing open ends, each of said open ends being closed by a cap so as to form a compartment therein especially to contain medicaments for pharmaceutical dosage.

Such a compartmented hard shell capsule may also be characterized in that said body part is a blister sheet and the cap part is a blister cover sheet sealed by heat and pressure thereto.

An embodiment of this group is shown in Figures 17 and 18. Figure 17 is an exploded perspective view of a compartmented capsule having a cap 2 and a body 1 with two compartments therein separated by a partition 5. Each of the compartments contain different medicaments. Figure 18 is a sectional view of the compartmented capsule of Figure 17 along line 18-18, when closed, and showing the complete separation of the different medicaments in compartments 11 and 12.

Figure 19 is a top plan view of an alternative compartmented capsule of the present invention showing two caps 2 axially abutting together at their open ends.

Figure 20 is a section of Figure 19 along line 20-20 showing the two caps 2 abutting together at their open ends. Contained within the caps 2 is a cylindrical body 1 which is separated by an integrally molded disc or partition 5 into two compartments 11, 12 for containing different medicaments. After filling the different medicaments into the compartments 11, 12 then each of the two caps 1 is telescopically joined over the body 1 from each open end so as to confine the different medicaments therein. For different therapeutic requirements one of the caps 1 could be made of materials that are soluble in the acid secretions of the stomach. The other cap 1 and the body 2 could be made of enteric materials. In this way, one of the medicaments in a compartment could be disintegrated within the stomach of the patient while the different medicaments in the other compartment could be disintegrated with the intestinal tract of the patient. By varying the materials and/or the thicknesses of the caps 1 and the body 2 there is obtainable a control of the disintegration rates of each compartment 11, 12.

It is another feature of this invention that cap part 1 and the body part 2 can be joined so as to provide a smooth surface in the joining area, J, in Figures 18, 19 and 20.

3. *Capsule package*

A capsule package consists of two or more capsules which are connected so that each subunit can be broken off for use. Capsule packages are not intended to be swallowed as a whole but rather to provide a convenient storage form, e.g. when each subunit has to be taken periodically. Therefore, the number of the totally connected subunits is not limited because of an easy-to-swallow requirement. The capsule packages may also be used to package the divisible capsule of group 1 and the compartmented capsule of group 2.

This embodiment is a hard shell capsule package dosage form having a plurality of connected capsules consisting of cap parts and body parts being joinable, characterized in that said capsules have a connection together, said connection being integrally molded with said capsules, and said connection further being breakable so as to separate the capsule into individual capsules especially for pharmaceutical dosage.

An embodiment of this group is shown in Figures 21 and 22. Figure 21 is a top plan view showing the capsules aligned along their axes. Figure 22 is a section of Figure 21 along line 22 showing the capsule bodies 1 connected by the lamellas 5 which consist of the same material as the capsule bodies 1 and which are manufactured simultaneously by die-molding techniques. The cap parts 2

of the dosage package are not connected to each other. Both the body parts 1 and the cap parts 2 may be provided with locking means to yield a separation-resistant arrangement.

Another embodiment of the capsule package is shown in the Figures 23 and 24. Figure 23 is a top plan view showing the capsule units arranged along a circle. Figure 24 is a section of Figure 23 along line 24-24 showing the capsule bodies 1 connected by the joinings 5 which may consist of the same material as the capsule bodies 1. These joinings 5 are manufactured simultaneously with the body parts 1. Both the body parts 1 and the cap parts 2 may also be provided with locking means.

Another embodiment of the capsule package is shown in the Figures 25 and 26 for the combination of two different medicaments. Figure 25 is a top plan view showing the capsules connected by the joining 5. Figure 26 is a section of Figure 25 along line 26-26 showing the capsule body parts 1 as formed simultaneously by die-molding with the body parts 1. The cap parts 2 are not connected. The capsules are shown as arranged in two rows so that the two medicaments can be filled in the body parts adjoining each other.

Blister packages are a known form of packaging for pharmaceutical dosages and other high-security products. It is another feature of the present invention that hard shell capsules can be formed from the blister package components of a blister sheet and a cover sheet which are sealed together by heat and pressure. After the blisters are filled with medicaments. In this invention the blister package components are manufactured from water soluble and edible hydrophilic polymers.

Figure 27 is a top plan view of an embodiment of a capsule blister package, showing the blister sheet 10 having separate blister compartments 11, 12, 13, 14 ... therein. Figure 28 is a section of Figure 27 along line 28-28 showing the blister sheet 10 to which a cover sheet 15 is sealed by pressure and heated so as to seal the blister compartments 11, 12, 13, 14 ... containing medicaments. At the juncture of the blister sheet 10 with the cover sheet 15 there may be perforations 16 so as to lose the separations of the blister compartments 13, 14 ... Figures 29, 30, 31 and 31 show alternative embodiments of capsule blister packages using the same reference numerals of Figures 27 and 28.

In Figures 29 and 30 the capsule blister package is shown having an elongated cross section of a conventional capsule form wherein the blister sheet 10 and the cover sheet 15 have symmetrical compartments 13, 14 therein.

In Figures 31 and 32 the capsule blister package is shown wherein each compartment 11, 12 is subdivided into subunits 17, 18, 19, 20, respectively, for containing different medicaments therein.

All of the embodiments of the present invention can be produced on injection-molding machines wherein the capsule material is melted in a plasticizing unit and then injected into a mold. When the mold is opened, the dosage parts are ejected. Film casting, injection-molding, compression-molding, blow-molding, deep drawing methods and other die-molding techniques may also be used for the production of the capsules of the present invention.

The present invention may also include sealing or bonding of the capsule when the capsule parts are joined. The sealing or bonding of the joined capsule parts provides an additional securing which further impedes separation and tampering which also makes the capsule liquid moisture vapor- and gas-tight.

The capsules produced in conformity with the present invention may be used for pharmaceutical purposes, as well as for the exact quantitative dosage of dyestuffs, chemicals, spices, fertilizing combinations for plants, fertilizers with protective substances, seeds, cosmestic, agricultural products, etc.

It should be understood that this disclosure is for the purpose of illustration only and that the present invention includes all modifications and equivalents falling within the scope of the appended claims.

Although in many of the illustrated embodiments of the invention the lamellae are shown near the upper end of the body parts, the lamellae can be provided further down the body parts, which can improve the closure of the cap and body parts.

CLAIMS

1. A divisible hard shell capsule in dosage form, having a plurality of connected subunits each comprising a joined or joinable cap part and body part, wherein the body parts are joined by connection elements and/or the cap parts are joined by connection elements, the connection elements being integrally moulded with the body parts and/or the cap parts, and the connection elements being breakable whereby the capsule may be divided into subunits.

2. A divisible hard shell capsule according to Claim 1, wherein the connection elements extend only between the body parts.

3. A divisible hard shell capsule according to Claim 1, wherein the connection elements extend only between the cap parts.

4. A divisible hard shell capsule according to Claim 1, wherein some connection elements extend between the body parts and other connection elements extend between the cap parts.

5. A divisible hard shell capsule according to any one of Claims 1 to 4, wherein the connection elements are lamellar.

6. A divisible hard shell capsule according to Claim 4, wherein the body parts or the cap parts are constituted by a blister sheet, and the cap parts or body parts, respectively, are constituted by a blister cover sheet sealed by heat and pressure to the blister sheet.

7. A divisible hard shell capsule according to Claim 1, wherein the subunits have cross-sections in the form of a square, a rectangle, a sector, a distorted rectangle in which one side is arcuate, a triangle, a triangle with a rounded apex, or a semicircle, different subunits within a single cap-

sule having the same or different cross-sections.

8. A divisible hard shell capsule according to Claim 1, substantially as hereinbefore described with reference to, or as illustrated in, Figures 1 to 4; Figures 5 and 6; Figures 7 and 8; Figures 9 and 10; Figures 11 and 12; Figures 13 and 14; or Figures 15 and 16 of the accompanying drawings.

9. A package comprising a plurality of connected hard shell capsules each formed of a joined or joinable cap part and body part, the capsules being connected by connection elements integrally moulded with the cap parts and/or the body parts, and the connection elements being breakable whereby the package may be divided into individual capsules.

10. A package according to Claim 9, wherein the connection elements extend only between the body parts.

11. A package according to Claim 9, wherein the connection elements extend only between the cap parts.

12. A package according to Claim 9, wherein the connection elements extend both between the body parts and between the cap parts.

13. A package according to any one of Claims 9 to 12, wherein the connection elements are lamellar.

14. A package according to Claim 9, wherein the cap parts or the body parts are constituted by a blister sheet, and the cap parts or body parts, respectively, are constituted by a blister cover sheet sealed by heat and pressure to the blister sheet.

15. A package according to Claim 9, substantially as hereinbefore described with reference to, or as illustrated in, Figures 21 and 22; Figures 23 and 24; Figures 25 and 26; Figures 27 and 28; Figures 29 and 30; or Figures 31 and 32 of the accompanying drawings.

16. A compartmented hard shell capsule in dosage form, comprising a joined or joinable cap part and body part, wherein the body part has one or more internal partition integrally moulded therein so as to from two or more compartments intended for medicaments within the body and the cap, when joined, for pharmaceutical dosage.

17. A compartmented hard shell capsule according to Claim 16, wherein the body part is generally tubular with an internal partition transverse to the longitudinal axis, each of the open ends of the partitioned tubular body part being closed or closable by a respective cap part so as to form a compartment therein.

18. A compartmented hard shell capsule according to Claim 16, substantially as hereinbefore described with reference to, or as illustrated in, Figures 17 and 18; or Figures 19 and 20 of the accompanying drawings.

19. A package comprising a plurality of compartmented hard shell capsules according to Claim 16 or 17, wherein the capsules are connected by integrally moulded connecting elements which are breakable whereby the package may be divided into individual compartmented hard shell capsules.

20. A package according to Claim 19, wherein the body parts are constituted by a blister sheet and the cap parts are constituted by a blister cover sheet sealed by heat and pressure to the blister sheet.

21. A package according to Claim 20, substantially as hereinbefore described with reference to, or as illustrated in, Figures 1 and 32 of the accompanying drawings.

22. A capsular product chosen from a divisible hard shell capsule according to any one of Claims 1 to 8, a package according any one of Claims 9 to 15, a compartmented hard shell according to any one of Claims 16 to 18 and a package according to any one of Claims 19 to 21, wherein the capsular product is made by injection moulding:

(i) from a hydrophilic polymer composition or a mixture of such polymers having a water content of from 5 to 25% by weight (calculated on the hydrophilic polymer composition) and, if formed from a gelatin composition, the gelatin composition having a water content of from 10 to 20% by weight (calculated on the gelatin composition); and/or

(ii) from a starch or a starch composition having a water content of 5 to 25% by weight (calculated on the starch composition).

23. A capsular product according to Claim 22, made from a starch composition.

24. A capsular product containing one or more of pharmaceuticals, dyestuffs, chemicals, spices, fertilizers, seeds, cosmetics and agricultural products, the capsular product being in accordance with Claim 22 or 23.

Printed in the UK for HMSO, D8818935, 4·85, 7102.
Published by The Patent Office, 25 Southampton Buildings, London, WC2A 1AY, from which copies may be obtained.